April 2019 Green Ribbon Science Panel Meeting
Pertinent Sections of the Safer Consumer Product Regulations & Final Statement of Reasons

Alternatives Analysis Threshold Determination

Safer Consumer Product Regulations

§ 69501.1
(12) "Alternatives Analysis Threshold" means whichever of the following is applicable:
(A) The Practical Quantitation Limit for a Chemical of Concern that is present in a Priority Product solely as a contaminant; or
(B) The applicable concentration, if any, specified by the Department under section 69503.5(c).

(52) "Practical Quantitation Limit" or "PQL" means the lowest concentration of a chemical that can be reliably measured within specified limits of precision and accuracy using routine laboratory operating procedures.
…
§ 69503.5(c) Alternatives Analysis Threshold. The Department may, for one or more product-chemical combinations, specify in the proposed and/or final Priority Products list an Alternatives Analysis Threshold concentration for any Chemical of Concern that is an intentionally added ingredient. The Department may also specify an Alternatives Analysis Threshold concentration greater than the applicable PQL for any Chemical of Concern that is a contaminant.
…
§ 69505.3. Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis.
(a) Notification Requirements. This article does not apply to a responsible entity's Priority Product for which the manufacturer submits an Alternatives Analysis Threshold Notification to the Department concurrently with the Priority Product Notification, or by the due date for the Preliminary AA Report for the Priority Product. Each notification must include:
(1) The name of, and contact information for, the person submitting the notification;
(2) The name of, and contact information for, any known responsible entity(ies);
(3) If different from paragraphs (1) and (2), the name of, and contact information for, the manufacturer(s) and importer(s) of the Priority Product;
(4)(A) A statement certifying that the Chemical(s) of Concern is/are present in the manufacturer's Priority Product only as contaminants and the concentration of each Chemical of Concern does not exceed the PQL for that chemical; or
(B) A statement certifying that the Chemical(s) of Concern does/do not exceed the Alternatives Analysis Threshold(s) specified by the Department under section 69503.5(c) for the Chemical(s) of Concern.
(5) If applicable, identification of the PQL for each Chemical of Concern in the Priority Product, and the information and method used to determine the PQL;
(6) The source of the Chemical(s) of Concern in the Priority Product;
(7) Information identifying and describing the Priority Product, the brand name(s) and labeling information under which the Priority Product is placed into the stream of commerce in California, and, if the Priority Product is a component of one or more assembled products, a description of the known product(s) in which the component is used;

(8) Laboratory analytical testing methodology and quality control and assurance protocols used to measure each Chemical of Concern in the Priority Product, and identification of the testing laboratory; and

(9) A demonstration and certification that the manufacturer meets and will continue to meet the criteria and conditions that are the basis for the exemption in this section.

(b) Burden of Proof. The manufacturer bears the burden of proof to demonstrate that the concentration of the Chemical(s) of Concern in its Priority Product does not exceed the applicable Alternatives Analysis Threshold.

(c) Notification Revisions. If any of the information listed in subsection (a) changes significantly, the manufacturer shall submit to the Department a revised Alternatives Analysis Threshold Notification within thirty (30) days of the change.

(d) Change in Product's Exemption Status. If the Priority Product no longer meets the criteria for an Alternatives Analysis Threshold exemption, the manufacturer shall notify the Department of this change within thirty (30) days of the change, and shall submit to the Department a Preliminary AA Report or an applicable Intent and/or Confirmation Notification under section 69505.2 within 180 days of the change.

(e) Determination of Exemption Eligibility. The exemption in subsection (a) does not apply if the Department notifies the person who submitted the Alternatives Analysis Threshold Notification that the information contained in the notification is inaccurate or inadequate to support an Alternatives Analysis Threshold exemption.

Final Statement of Reasons

The PQL as the AA Threshold for contaminant chemicals will be practical and implementable. This will provide the certainty that the regulated community needs to ensure compliance and the success of these regulations. This default AA Threshold will not require responsible entities to hire toxicologists to justify product-specific thresholds that are no longer part of determining the AA Threshold. Once the PQL is known for a product-chemical combination, this will allow for better communication throughout the supply chain.

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Section 69501.1(a)(12) defines "Alternatives Analysis Threshold" to mean the Practical Quantitation Limit (PQL) for a Chemical of Concern that is a contaminant in a Priority Product, or the concentration (if any) specified by DTSC on a product/chemical specific basis during the Priority Product listing process (under section 69503.5(c)) for either a contaminant or an intentionally added Chemical of Concern. The public review and comment period for each proposed Priority Product listing will give interested parties the opportunity to present information to DTSC to support: (i) an AA Threshold proposed by DTSC in the proposed Priority Product listing; (ii) a request that DTSC revise or eliminate the AA Threshold proposed by DTSC; or (iii) a request that DTSC specify an AA Threshold in the Priority Product listing in the event that DTSC has not proposed an AA Threshold.

This definition, in its entirety, is necessary to provide an appropriate threshold concentration below which a responsible entity is not required to complete an AA. The AA Threshold will be a default value equal to the PQL if the chemical is a contaminant, or will be established through rulemaking under the Administrative Procedure Act if DTSC chooses to set an AA Threshold for a particular Priority Product-Chemical of Concern. This is necessary to allow DTSC the flexibility to set an AA Threshold for an

intentionally added chemical when appropriate to do so, and to set the AA Threshold higher than the PQL for contaminants when it is appropriate to do so.

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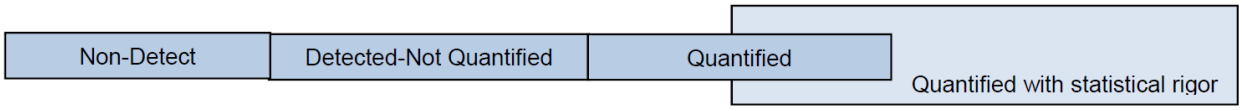
Section 69501.1(a)(52) defines "Practical Quantitation Limit" or "PQL" to mean the lowest concentration of a chemical that can be reliably measured with statistical rigor (*i.e.*, within specified limits of precision and accuracy) using routine laboratory procedures. This provision is necessary because the default AA Threshold for contaminants is defined as the PQL. If a Priority Product contains the Chemical of Concern as a contaminant below this concentration, an AA is not required. Additional information concerning the AA Threshold and the AA Threshold exemption, and their necessity, is provided in the statement of reasons for sections 69501.1(a)(1)(12), (13), and (26) and section 69505.3.

Figure 1. Practical Quantitation Limit



§ 69505.3. Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis

The processes in Articles 2 and 3 are designed to identify chemicals (as Candidate Chemicals) that have adverse impacts on public health and/or the environment if exposures to the chemicals occur; and identify and prioritize product-chemical combinations for which there is the potential for exposures to the Candidate Chemicals in the product potentially resulting in adverse impacts. In Article 3, consumer products containing chemicals listed as Candidate Chemicals under Article 2 will be prioritized based on potential adverse public health and environmental impacts, potential exposures, and relevant factors. The Candidate Chemical(s) that is/are the basis for listing a product as a Priority Product become the Chemical(s) of Concern for that product. An AA under Article 5 must be performed for each product that is a Priority Product by one of the responsible entities for the product. A Priority Product is exempted from Article 5 AA requirements if the concentrations of the Chemical(s) of Concern in the Priority Product do not exceed the applicable AA Threshold(s) (if AA Thresholds have been set for the Priority Product-Chemical of Concern) and the manufacturer of the product submits an AA Threshold Notification to DTSC.

Section 69501.1(a)(12) defines the AA Threshold as either: (i) the Practical Quantitation Limit (PQL) for a Chemical of Concern present in the Priority Product solely as a contaminant; or (ii) the applicable concentration, if any, specified by DTSC during the Priority Product listing process under section 69503.5(c). Given the Chemicals of Concern's adverse public health and environmental impacts, it would not be prudent for DTSC to establish a threshold above the PQL absent information demonstrating that a higher level is appropriate. Establishing the AA Threshold at the PQL for Chemicals of Concern present in Priority Products solely as contaminants – and having no default AA Threshold for intentionally added Chemical(s) of Concern – in effect, requires that manufacturers ask whether the Chemical(s) of Concern in the products that they manufacture is/are necessary – both for chemicals knowingly used to manufacturer a product and other chemicals present in a product that can be reasonably and reliably detected and measured.

If information demonstrates that an AA threshold is necessary and appropriate for an intentionally added Chemical of Concern in a particular product or that an AA Threshold above the PQL is necessary

and appropriate for a contaminant, such an AA Threshold could be established at the time of the Priority Product listing. Section 69503.5(c) specifies that DTSC may for one or more product-chemical combinations specify in the proposed or final Priority Products list an AA Threshold concentration for any Chemical of Concern that is an intentionally added ingredient. It further provides that DTSC may specify an AA threshold concentration greater than the default AA Threshold (*i.e.*, the PQL) for any Chemical of Concern that is a contaminant.

In most cases, DTSC will list products as Priority Products because of Chemicals of Concern that are intentionally used to manufacture the product. Most of the products covered by any given Priority Product listing will have the Chemicals of Concern as intentionally added ingredients. DTSC has determined that it is not appropriate or necessary to establish an across-the-board default AA Threshold for intentionally added ingredients in Priority Products because: (i) the manufacturer knows the Chemical of Concern is present in their product without the need for laboratory testing; and (ii) as part of the product prioritization process, DTSC has determined that the Chemical of Concern is typically present in products covered by the Priority Product listing in concentrations that pose potential exposures and potential adverse impacts and so an AA followed by regulatory responses is needed to address those adverse impacts.

It is possible, however, that some products covered by a Priority Product listing will have the Chemical of Concern present either: (i) as an intentionally added ingredient but at much lower concentrations than most other products covered by the same Priority Product listing; or (ii) solely as contaminants. If DTSC becomes aware (either prior to issuing the proposed Priority Product listing or upon receipt of public comments) of the existence of products containing the Chemical of Concern at relatively small concentrations compared to most other products covered by the same Priority Product listing, the regulations (at section 69503.5(c)) give DTSC the latitude to establish an AA Threshold for that particular Priority Product listing that would allow such products (with lower concentration Chemicals of Concern) to be exempted under section 69505.3 from the AA requirements – the AA requirements would still apply to the other products covered by the same Priority Product listing that contain the Chemical of Concern at higher concentration levels.

In the instance where the Chemical of Concern is present in a particular manufacturer's Priority Product solely as a contaminant, the manufacturer can submit a notification under section 69505.3 for an AA Threshold exemption if the concentration of the Chemical of Concern in their product does not exceed the PQL. Providing a default AA Threshold for contaminant Chemicals of Concern is necessary because manufacturers do not always have knowledge of and/or control over factors (*e.g.,* contaminants in raw materials or recycled materials) that may lead to the presence of the contaminant in their products – and so in many cases testing will be needed to determine if the Chemical of Concern is present in the product. As is discussed below, the PQL was determined to be the most workable and appropriate AA Threshold for contaminants, at least as a default threshold. In some cases, a higher AA Threshold may be appropriate for a contaminant Chemical of Concern, and section 69503.5(c) gives DTSC the latitude to address this situation as part of the Priority Product listing process.

If DTSC decides to list a product as a Priority Product on the basis of a contaminant Chemical of Concern, this will likely be because the contaminant is frequently found in products covered by the Priority Product listing in concentrations that present potential adverse impacts and potential exposures – in some cases this could be at the PQL and in other cases it could be at a much higher concentration level. If DTSC determines an AAT above the PQL is warranted for such a Priority Product, the regulations again provide the latitude for DTSC to set a higher AA Threshold.

If DTSC determines an AA Threshold for an intentionally added Chemical of Concern, or an AA Threshold above the PQL for a contaminant Chemical of Concern, is warranted for a particular Priority Product-Chemical of Concern, DTSC may propose the AA Threshold as part of the proposed Priority Product listing. In some cases, such a determination may be made subsequent to issuance of the proposed Priority Product listing based on information received during the public comment period – in this instance, DTSC would revise the proposed Priority Product listing to reflect the proposed AA Threshold and reissue the proposed listing for public comment on the proposed AA Threshold prior to issuing a final Priority Product listing. (The same process would be followed if DTSC decided to revise or eliminate a previously proposed AA Threshold in response to public comments.)

The provisions of the regulations pertaining to setting AA Thresholds are necessary to ensure that in the face of limited resources and time constraints, DTSC does not have to establish a case-by-case AA Threshold for each Priority Product-Chemical of Concern, while giving DTSC the ability to do so when it determines a Priority Product-Chemical of Concern specific AA Threshold is warranted. This approach also avoids the potential for exempting from the AA and regulatory response processes a Priority Product-Chemical of Concern that presents concerns that need to be addressed but that would not be if the regulations set an across-the-board AA Threshold (*e.g.,* 0.01% or 0.1%).

For purposes of the default AA Threshold for a contaminant, the regulations (at section 69505.1(a)(25)) define the Practical Quantitation Limit (PQL) to mean "the lowest concentration of a chemical that can be *reliably* measured within specified limits of precision and accuracy using routine laboratory operating procedures." (Emphasis added.)

While the definition specifies that the PQL is the lowest concentration of a chemical that can be "reliably measured," there is a lower limit – that is the concentration at which instruments will detect the presence of a contaminant (*e.g.,* a Chemical of Concern) with consistent confidence. If a chemical is detected at this lower level but cannot be reliably quantified this is commonly referred to as the method detection limit (MDL). This level can vary from laboratory to laboratory. The fact that the chemical concentration cannot be reliably quantified at these lower levels makes the MDL unsuitable for policy setting and/or regulatory decision-making. Similarly, there is a higher concentration than the PQL at which a chemical concentration may be quantified. However, because some chemicals (*e.g.*, carcinogens) cause adverse impacts at very low levels, at or near zero, it is unsuitable to use a higher default level of quantification for policy setting and/or regulatory decision-making. It is important to note that chemicals may have adverse impacts below levels that can be measured and/or quantified.

The concentrations between the PQL and MDL are real and provide indications of presence; however, because of the inability to reliably quantify contaminants at the MDL, the MDL is used as the starting point to establish a more reliable concentration — the PQL. There are two primary approaches to establish the PQL using the MDL: (1) the laboratory performance method; and (2) the multiplier method. In the laboratory performance method, the MDL is used to extrapolate the PQL through the application of statistically and scientifically acceptable methods. In essence, this method establishes the PQL based on the performance of a representative number of laboratories that can reliably quantify the concentration using appropriate analytical methods. This method takes into account the practicability of laboratories quantifying the identified concentration. The multiplier method is based on multiplying the MDL by a factor ranging from three (3) to ten (10). This takes into account the variability and uncertainty that can occur at the MDL. The MDL multiplier method may be most suitable when a representative number of laboratories are not available to establish a more rigorous PQL. Historically, the laboratory

performance method has been used to validate PQLs that were originally developed using the MDL multiplier method.

The PQL, as defined in the proposed regulations, is consistent with U.S. EPA's approach and takes into account the quantitation limits, precision and biases, normal operations of laboratories, and the programmatic needs to have a sufficient number of laboratories available to conduct compliance monitoring. The PQL is, in effect, the point where an occurrence or presence of a contaminant (*e.g.*, a Chemical of Concern) can be reliably quantified by most laboratories for specific chemical contaminants using day to-day routine laboratory operating procedures.

In general, the use of the PQL as a point of departure is advantageous over a default de minimis threshold (*e.g.*, 0.01% or 0.1%) that is applied across the board to all product-chemical combinations – because the PQL is the lowest quantifiable concentration, is medium-specific, can be achieved by a representative number of laboratories, and provides a uniform measurement of concentrations that can be adjusted as technological advances are made. As laboratory methods and limits of detection are lowered due to advances in testing or analytical advancements, the PQL can be lowered, if necessary to address contaminants that have adverse effects at much lower concentrations.

For the reasons cited above, DTSC believes the PQL is the most protective default AA Threshold level for contaminants, while simultaneously taking into account the practicality of reliably detecting and confirming the quantifiable levels of specific contaminants. The use of a specific MDL-derived procedure for calculating the PQL also provides a mechanism by which DTSC and stakeholders can recognize and take advantage of analytical technologies to re-evaluate method-specific and matrix specific PQLs on an as-needed basis.

Section 69505.3, in its entirety, is necessary to provide an exemption from the requirement to conduct an AA under Article 5, if the Chemical of Concern in a product that is listed as a Priority Product does not exceed the applicable AA Threshold (if one is established in the regulations or subsequently by DTSC). To effectuate the exemption the manufacturer of the product must submit an AA Threshold Notification to DTSC so that DTSC, other responsible entities for the product, and interested parties are made aware that the manufacturer's product is exempt and know not to expect an AA for the product.

As explained above, a default AA Threshold is available for a Priority Product only if the Chemical of Concern is present in the product solely as a contaminant, and the concentration of the Chemical of Concern does not exceed the PQL for the chemical. If during the product prioritization process, DTSC determines that an AA Threshold is needed for a particular intentionally added chemical in a particular product or that the AA Threshold for a contaminant should be set higher than the PQL – this can be addressed in the rulemaking for that Priority Product listing. That is, DTSC has the authority to establish specific AA Thresholds on a case-by-case basis for intentionally added chemicals and contaminants.

Section 69505.3 specifies the information that must be included in an AA Threshold Notification. The manufacturer is required to notify DTSC if the information in the AA Threshold Notification significantly changes, or the product no longer meets the criteria for an AA Threshold exemption.

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Section 69505.3(d) requires the manufacturer to notify DTSC, within thirty (30) days, if the product no longer meets the criteria for an AA Threshold exemption. In addition, the manufacturer is required to submit a Preliminary AA Report or an applicable Intent and/or Confirmation Notification under section

69505.2 to DTSC within 180 days of the change in status. Notification of a change in a product's exemption status is necessary so that manufacturers and DTSC are both basing decisions on current information. This provision is necessary to inform DTSC, other responsible entities for the product, and interested parties that the affected Priority Product is now subject to the AA requirements, and so that DTSC knows when the Preliminary AA Report is due – so that compliance actions can be taken if the AA Report is not received by the due date. It is also necessary to prevent a manufacturer from relying on an exemption for which it no longer qualifies. The 180-day time period allowed for submitting a Preliminary AA Report or an Intent and/or Confirmation Notification is consistent with comparable due dates in the regulations and ensures that the AA process is not unduly delayed.

Section 69505.3(e) disallows the AA Threshold exemption if DTSC notifies the person who submitted the AA Threshold Notification that the information or findings contained in the notification are inaccurate or inadequate to support an AA Threshold exemption. Although DTSC is not required to approve the AA Threshold Notification, if DTSC determines that the information or findings submitted with the AA Threshold Notification are not adequately substantiated, the exemption may be invalidated by DTSC. This provision is necessary to put manufacturers on notice that the AA Threshold Notification must include information that substantiates their findings and if necessary DTSC may reject the AA Threshold exemption if the findings are not substantiated. This provision is also necessary to ensure that Priority Products that do not actually qualify for an exemption proceed into the AA process.

Alternative Analysis Review Process

Safer Consumer Products Regulations

§ 69505.9. Department Review and Determinations for AA Reports and Work Plans.

(a) Review Criteria. In reviewing AA Reports and Alternate Process AA Work Plans for compliance with the substantive and administrative requirements of this article, the Department shall consider:
(1) Whether the AA Report or Alternate Process AA Work Plan was submitted timely;
(2) Whether, and to what extent, the responsible entity considered and addressed all applicable provisions of this article pertaining to the preparation and submittal of an AA Report or Alternate Process AA Work Plan, whichever is applicable;
(3) Whether, and to what extent, the responsible entity demonstrated that the conclusions of the AA were based on reliable information, when applicable.

(b) Preliminary AA Reports and Alternate Process AA Work Plans.
(1) Within sixty (60) days of receiving a Preliminary AA Report or Alternate Process AA Work Plan, the Department shall review the report or work plan for compliance with this article, and issue a notice of compliance, notice of deficiency, notice of disapproval, or notice of ongoing review.
(2) Notice of Deficiency.
(A) The Department shall specify in a notice of deficiency the areas of deficiency, the information required to cure the deficiency(ies), and the due date for submitting the necessary information, which may not exceed sixty (60) days from the date the notice of deficiency is issued. The responsible entity shall submit a revised report or revised work plan, whichever is applicable, by the due date specified, and address the areas of deficiency.

(B) Within thirty (30) days of receipt of the additional information requested in the notice of deficiency, the Department shall issue a notice of compliance, a notice of disapproval, or a notice of ongoing review for the revised report or revised work plan.
(3) Notice of Disapproval. If the revised report or revised work plan does not fully address the identified areas of deficiency, the Department shall issue a notice of disapproval. The Department shall also issue a notice of disapproval if a revised report or revised work plan is not submitted by the due date specified under paragraph (2)(A). If the revised report or revised work plan is disapproved, the Department shall explain the basis for the disapproval. A disapproved revised report or revised work plan is not in compliance with section 69505.1(b).
(4) Notice of Compliance. The Department shall specify in a notice of compliance for a Preliminary AA Report or Alternate Process AA Work Plan the due date for submitting the Final AA Report. The Department shall specify a due date twelve (12) months from the date the Department issues the notice of compliance, except that the Department may specify an extended due date for submission of the Final AA Report if it determines based on information in the Preliminary AA Report or Alternate Process AA Work Plan that more time is needed. The Department may also specify an extended due date for submission of the Final AA Report if the responsible entity submits a request under section 69505.7(k)(1)(B).

(c) Final AA Reports and Abridged AA Reports.
(1) Within sixty (60) days of receiving an AA Report Addendum, the Department shall review the Final AA Report or Abridged AA Report, including the AA Report Addendum, for compliance with this article, and shall issue a notice of compliance, notice of deficiency, notice of disapproval, or notice of ongoing review. If no AA Report Addendum is required under section 69505.8, the Department shall complete its review of the Final AA Report or Abridged AA Report within sixty (60) days of whichever of the following dates is applicable:
(A) The close of the public comment period, if no public comments are received; or
(B) Thirty (30) days after the close of the public comment period, if the Department determines after reviewing the public comments that there are no issues that need to be addressed in an AA Report Addendum.
(2) Notice of Deficiency.
(A) The Department shall specify in a notice of deficiency the areas of deficiency, the information required to cure the deficiency(ies), and the due date for submitting the necessary information to complete the Final AA Report or Abridged AA Report, which may not exceed sixty (60) days from the date of the notice of deficiency. The responsible entity shall submit a revised Final AA Report or revised Abridged AA Report by the due date specified, and address all areas of deficiency. The responsible entity may request and the Department may approve, under section 69505.1(c), a one-time extension of not more than ninety (90) days for submission of the revised Final AA Report or revised Abridged AA Report to correct the deficiencies.
(B) Within sixty (60) days of receipt of the requested additional information, the Department shall issue a notice of compliance, a second notice of deficiency, or a notice of ongoing review.
1. If the Department issues a second notice of deficiency, the Department may grant no more than thirty (30) days for submission of the requested information.
2. Within sixty (60) days of receipt of the additional information requested in the second notice of deficiency, the Department shall issue a notice of compliance, a notice of disapproval, or a notice of ongoing review for the revised Final AA Report or revised Abridged AA Report.
(3) Notice of Disapproval. If the revised Final AA Report or revised Abridged AA Report does not fully address the areas of deficiency identified in the second notice of deficiency, the Department shall issue a notice of disapproval. The Department shall also issue a notice of disapproval if a revised Final AA

Report or revised Abridged AA Report is not submitted by the due date specified under paragraph (2)(A) or paragraph (2)(B)1., whichever is applicable. If the revised Final AA Report or revised Abridged AA Report is disapproved, the Department shall explain the basis for the disapproval. A disapproved revised Final AA Report or revised Abridged AA Report is not in compliance with section 69505.1(b).

(d) Notice of Ongoing Review. The Department shall specify in a notice of ongoing review the estimated date by which the Department expects to issue a notice of compliance or notice of deficiency, which shall be based on its available resources and the complexity of the document under review.

(e) Issuance of Notices. All notices issued by the Department under this section shall be issued to the person who submitted the document, and a copy of the notice shall be sent by the Department to all persons identified in the document under subsections (c)(2) and (c)(3) of section 69505.7.